K001810

AUG 1 4 2000

FlexSite Diagnostics, Inc.

510(K) SUMMARY

April 19, 1997

FLEXSITE DIAGNOSTICS®, INC.
3543 SW CORPORATE PARKWAY
PALM CITY, FL 34990

PHONE: 561 221-8893
FAX: 561 221-9671

CONTACT PERSON: Donald R. Stone
McKenna and Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Phone: 202 496-7620
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TRADE NAME: UriSite™ Microalbumin

COMMON NAME: Home sampling kit for self-monitoring of urinary microalbumin

CLASSSIFICATION: Not listed.

PREDICATE DEVICE: EZCHEK™ Sample Collection Kit (K971919).

DESCRIPTION: The device is a kit containing the materials required to collect a dried urine sample on a urine paddle with a special absorbent material and mail it to a laboratory for determination of its microalbumin/creatinine ratio. The kit contains a test request form with attached urine paddle, Instructions for Use, a sealable plastic bag, a return envelope and labels for returning results to the patient and/or his/her doctor.

INTENDED USE: Urisite™ Microalbumin is an at-home or in-office sample collection kit for the purpose of screening for kidney dysfunction and monitoring therapy in diabetic adults. Abnormal results must be reported to and evaluated by your physician.

SUMMARY OF TECHNOLOGICAL SIMILARITIES AND DIFFERENCES:

SIMILARITIES: The key concept of collecting a dried urine sample at home using the kit and sending the sample to a licensed clinical lab for analysis which uses standard laboratory methods in a regulated and quality controlled environment is functionally the same as collecting a dried blood sample using the EZCHEK™ kit and sending in the sample for HbA1c analysis. Collecting a urine sample is easier and less invasive than collecting a finger stick blood sample.

DIFFERENCES:

1. The methods of analysis of microalbumin and creatinine have only been changed to add more sample to the reagent to compensate for the dilution resulting from eluting the sample from the absorbent material on the urine paddle.
2. The filter paper for absorbing blood has been replaced by a material suitable for absorbing and drying urine. This material is mounted on a plastic holder (paddle) for ease of handling.

NONCLINICAL PERFORMANCE DATA: The dried urine method was shown to give accurate results compared to neat urine as judged from the following correlation data: dry = 0.933*neat +68; r = 0.995; n = 41 for paddles dried and kept 7 days at room temperature. The precision of measuring dried urine spots was typically 3.8% within run. Total precision per NCCLS EP-5A over a 20 day study was 7% at 365 ug/mg, and 1346 ug/mg. The stability of dried urine paddles at temperature extremes was shown to be compatible with expected mailing conditions.

CLINICAL PERFORMANCE DATA: Kits were evaluated in four sites to confirm the ease of use by medical professionals in an office setting as well as by patients in the office and the home. Results were also correlated to neat urine. Correlation for office paddles dipped by patients was: dry = 1.013* neat -3.6507; r = 0.980; n = 80. Correlation for office paddles dipped by nurses was: dry = 0.9969* neat + 1.6234, r = 0.977, n = 77. Patients were also given a second kit to take home. They used the kit the next day and mailed the samples to the FlexSite laboratory. These results correlated reasonably well to the neat sample taken the previous day considering the delay. However, the primary purpose of the second kit for home sampling was to test user friendliness in the home setting and the mailing aspects. The patients filled out questionnaires regarding the ease of use etc. Their comments indicated that the kit is acceptable as designed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 4 2000

Mr. Robert A. Ray
Vice President & COO
FlexSite Diagnostics, Inc.
3543 SW Corporate Parkway
Palm City, Florida 34990

Re: K001810
Trade Name: FlexSite Diagnostics, Inc. UriSite™ Urine Collection Kit for Microalbumin/Creatinine Testing
Regulatory Class: II Product Code: JIR
II CGX
Dated: June 14, 2000
Received: June 15, 2000

Dear Mr. Ray:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K001810

Device Name: UriSite ™ Microalbumin (Dried Urine Sample Collection Kit)

Indications for Use:

UriSite™ Microalbumin is an at-home or in-office urine sample collection kit for the purpose of screening for kidney dysfunction in diabetic adults. Abnormal results must be reported to and evaluated by your physician.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001810

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)